



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0165; FRL-9901-95]

D-Glucopyranose, oligomeric, decyl octyl glycosides; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of D-Glucopyranose, oligomeric, decyl octyl glycosides when used as an inert ingredient (surfactant) in antimicrobial formulations (food-contact surface sanitizing solutions) applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. Lewis & Harrison, on behalf of BASF Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of D-Glucopyranose, oligomeric, decyl octyl glycosides.

DATES: This regulation is effective **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Objections and requests for hearings must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0165, is available at <http://www.regulations.gov> or at the

Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: RDNRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0165 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0165, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of June 5, 2013 (78 FR 33785) (FRL-9386-2), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10545) by Lewis & Harrison, LLC, 122 C St., NW., Suite 740, Washington, DC 20001 on behalf of BASF Corporation, 100 Park Ave., Florham Park, NJ 07932. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of alkyl (C₈-C₁₀) polyglucosides (CAS Reg. No. 68515-73-1) when used as an inert ingredient (surfactant) in antimicrobial formulations (i.e., food contact surface sanitizing solutions) applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

That document referenced a summary of the petition prepared by Lewis & Harrison, LLC, on behalf of BASF Corporation, the petitioner, which is available in the

docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

EPA is establishing a tolerance using a different chemical name than the one requested by the petitioner for the reasons discussed in Unit V.B.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include

occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for D-Glucopyranose, oligomeric, decyl octyl glycosides including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with D-Glucopyranose, oligomeric, decyl octyl glycosides follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by D-Glucopyranose, oligomeric, decyl octyl glycosides as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

In order to make a safety finding on D-Glucopyranose, oligomeric, decyl octyl glycosides, EPA used data on the chemical itself and structurally similar chemicals--alkyl (C₁₂-C₁₄) polyglycosides and alkyl (C₁₀-C₁₆) polyglycosides (also known as D-glycopyranose, oligomeric, C₁₀-C₁₆- alkyl glycosides) . These three chemicals differ from one another only in the length of the alkyl chain. Given these structural similarities, these chemicals are expected to have similar toxicological characteristics. Therefore, data on alkyl (C₁₀-C₁₆) polyglycosides and alkyl (C₁₂-C₁₄) polyglycosides have been used to make a safety finding on alkyl (C₈-C₁₀) polyglycosides. For ease of reading, alkyl polyglycosides will be collectively known throughout the document as “APG” with the specific carbon chain length identified as “(C_x-C_x),” when appropriate.

Acute studies indicate low acute oral and dermal toxicity. Studies using APG (C₈-C₁₀) did not show evidence of eye or skin irritation. Repeat dose studies for APGs include a 90-day gavage study, a 14-day dermal, a reproduction study, and a developmental study. In the 90-day rat oral (gavage) study APG (C₁₂-C₁₄) was administered at dose

levels of 0, 250, 500, or 1,000 milligram/kilogram/day (mg/kg/day) for 5 days/week.

There were no treatment-related adverse effects on body weight, body weight gain, food consumption, hematological or clinical chemistry parameters, or organ weights. Adverse treatment-related effects were limited to irritation in the forestomach in both males and females receiving 500 or 1,000 mg/kg/day. Effects were reversible following the cessation of treatment, but not reversible during treatment. Because humans do not have a forestomach that serves as a storage reservoir as in rodents, the effects seen in the rat forestomach are likely to be significantly more severe than what would be expected from the compound in the glandular stomach in humans and subsequently, have less relevance to humans. Therefore, the EPA determined the systemic oral toxicity NOAEL was 1,000 mg/kg/day. A LOAEL was not determined.

A 14-day dermal study on APGs (C₈–C₁₀) was conducted on rabbits (New Zealand white) at doses of 0, 60, 180, 540, 1,500, and 3,000 mg/kg/day. While skin irritation was observed at doses above 180 mg/kg/day and changes in hematological and clinical parameters and testicular degeneration were observed at the dose levels of 1,500 and 3,000 mg/kg/day, these effects are likely attributable to stress and inflammation due to the severe irritation caused by the test substance and therefore a NOAEL for systemic effects was not established.

A 1-generation reproductive screening study on APG (C₁₀–C₁₆) was conducted on male and female rats following daily administration (gavage) of 100, 300, and 1,000 mg/kg/day. No effects indicative of general toxicity were observed in parental animals. Relative and absolute weights of testes, epididymides, and seminal vesicles did not differ between test and control animals. No reproductive parameters were affected including

mean litter weights, mean pup weights, sex ratios, and gestation periods. Pre-weaning clinical signs showed no treatment-related effects in pups, nor did necropsy reveal any effects in decedent or F1 pups. Macroscopic examination revealed no difference between treated and control animals. A NOAEL of 1,000 mg/kg/day for reproductive effects can be deduced.

In a rat developmental toxicity study, APG (C₁₂-C₁₄) was administered by gavage at dose levels of 0, 100, 300, and 1,000 mg/kg/day on gestation days 6 to 15. No treatment-related maternal deaths; clinical signs; or decreases in mean body weight, weight gain, corrected weight gain, or gross lesions were observed in this study. In addition, there were no treatment-related developmental effects (e.g., external abnormalities, visceral abnormalities, or skeletal malformations/variations). Therefore, the developmental and maternal NOAEL is 1,000 mg/kg/day. A LOAEL was not determined.

No immunotoxicity or neurotoxicity studies are available in the database; however, APGs (C₈-C₁₀) are unlikely to produce neurotoxicity or evoke immunological response given the lack of any toxicity, including any immunotoxicity or neurotoxicity, at high doses (1,000 mg/kg/day). Mutagenicity studies on various chain lengths of APGs were negative indicating that APGs are not likely to be mutagenic. No carcinogenicity studies are available on APGs; however, APGs are not expected to be carcinogenic based on lack of mutagenicity, lack of any systemic toxicity at doses up to and including 1,000 mg/kg/day, and the rapid metabolism of these chemicals to sugars and alcohols and excretion from the body.

B. Toxicological Points of Departure/Levels of Concern

Metabolism studies on structurally related chemicals indicate that the body can effectively metabolize D-glucopyranose, oligomeric, C₁₀-C₁₆-alkyl glycosides to water-soluble substances (predominantly sugar and various alcohols) that are readily excreted from the body. No adverse effects were seen any of the repeat dose studies conducted via the oral route of exposure at or above the limit dose. No endpoint of concern was identified based on the available studies in the database.

C. Exposure Assessment

Because no endpoint of concern was identified based upon available data, a qualitative risk assessment was conducted.

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to D-Glucopyranose, oligomeric, decyl octyl glycosides, EPA considered exposure under the proposed exemption from the requirement of a tolerance. For purposes of this action, EPA qualitatively assessed dietary exposures from D-Glucopyranose, oligomeric, decyl octyl glycosides as follows:

Dietary exposure could potentially occur from consuming foods directly treated with pesticide products containing the inert ingredient. In addition, dietary exposure to APGs could occur as a result of contact with surfaces treated with antimicrobial formulations containing the inert ingredient, including food-contact surfaces in public eating places, dairy-processing equipment, or food-processing equipment and utensils. Dietary exposure may also come from consuming animal products from animals exposed to the inert ingredient via pesticide application or from eating feed treated with pesticide products containing the inert ingredient.

2. *Dietary exposure from drinking water.* Dietary exposure from drinking water to D-Glucopyranose, oligomeric, decyl octyl glycosides can occur by drinking water that has been contaminated by contact with pesticide treated areas, such as countertops. Since an endpoint for risk assessment was not identified, a quantitative dietary exposure assessment from drinking water for D-Glucopyranose, oligomeric, decyl octyl glycosides was not conducted.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). APGs are used in laundry detergents, hard surface and household cleaners, as rinse aids in dishwashers and in personal care products. Non-dietary exposure could result from both pesticidal and non-pesticidal uses.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found D-Glucopyranose, oligomeric, decyl octyl glycosides to share a common mechanism of toxicity with any other substances, and D-Glucopyranose, oligomeric, decyl octyl glycosides does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that D-Glucopyranose, oligomeric, decyl octyl glycosides does not have a common mechanism of toxicity with other substances. For information regarding EPA's

efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. The toxicity database for APGs contains several acute studies, a 90-day oral toxicity study, a 14-day dermal study, a developmental toxicity study, and a reproductive screening toxicity study. No hazard was identified based on those studies. The toxicity database does not contain a carcinogenicity study, an immunotoxicity study, or a neurotoxicity study, but for the reasons stated in Unit IV.A., the Agency has concluded that there are no concerns for carcinogenicity, immunotoxicity, or neurotoxicity for this chemical. No developmental or reproductive effects were seen in the available studies. Thus, there is no residual uncertainty regarding prenatal and/or postnatal toxicity of D-Glucopyranose, oligomeric, decyl octyl glycosides.

Based on this information, there is no concern at this time for increased sensitivity to infants and children to D-Glucopyranose, oligomeric, decyl octyl glycosides when used as an inert ingredient in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on D-Glucopyranose, oligomeric, decyl octyl glycosides, EPA has determined that there is a reasonable

certainty that no harm to any population subgroup will result from aggregate exposure to D-Glucopyranose, oligomeric, decyl octyl glycosides under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.940(a) for residues of D-Glucopyranose, oligomeric, decyl octyl glycosides when used as an inert ingredient in antimicrobial food-contact surface sanitizing solutions is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. Revisions to Petitioned-For Tolerances

Alkyl (C₈-C₁₀) polyglycosides and D-Glucopyranose, oligomeric, decyl octyl glycosides are alternate names for the chemical with the CAS Reg. No. 68515-73-1 and therefore, represent the same chemical. EPA is using the latter name because it is the one used in the Chemical Abstract (CA) Index and the one EPA has used to establish other exemptions from the requirement of tolerance for this chemical.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for D-Glucopyranose, oligomeric, decyl octyl glycosides (CAS Reg. No. 68515-73-1) when used as an inert ingredient (surfactant) in antimicrobial formulations (i.e., food contact surface sanitizing solutions) applied to food-contact

surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 22, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.940, add alphabetically the following entry to the table in paragraph

(a) to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
* * *	* *	* *
D-Glucopyranose, oligomeric, decyl octyl glycosides	68515-73-1	None
* * *	* *	* *

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